# FRANCESC MAINTERNATIONAL

Publishing
Consulting
Licensing & Acquisition
SWITCH Process
Management

# FRANCESCO INTERNATIONAL

- SWITCH® Newsletter (1994)
  - 6 years old, subscribers in 24 countries
- SWITCH® Market Impact Studies (1995)
- Max Planning Series
  - Max the Molecule® (1996)
  - Max the Portfolio® (1997)
- SWITCH Process Management (1997)
  - The SWITCH Group®

## **Evolving Understanding of Rx-to-OTC Switches**

## Francesco International focuses on Rx-to-OTC Switches.

#### We cover:

- molecules -- regulatory, marketing
- public benefit or risk, cost savings
- independent appraisal of product portfolios
- global/country product categories, products
- success factors for switching, etc.

FRANCESCO
INTERNATIONAL
4 Sloan Street, Suites C-G, South Orange, NJ 07079
Tele. (973) 761-5566 Fax (973) 761-6996
Visit us on the web at RxtoOTCSwitch.com

#### We are now on the World Wide Web at Frank om







The principal mission of Francesco International is the responsible enhancement of self medication.

A specific business goal of Francesco International is to be the world's expert on the increasingly important subject of Rx-to-OTC switches. We currently possess the world's largest database of analyzed knowledge on the subject of current and future Rx-to-OTC switches in major world markets.

Or on the WWW at RxToOTCSwitch.com

## The Slowing Down of Rx-to-OTC Switches

(1995-1999 in SWITCH® Major Markets)

Year	US	UK	Canada	Germany	France	Australia	Jap in	Total
1995	6	5	2	2	0	3	3	21
1996	4	3	1	7	5	0	0	20
1997	3	0	5	6	3	0	4	21
1998	0	3	1	2	4	0	C	10
1999	1	0	3	3	3	1	The state of the s	12

Molecule switches only, for example nicotine patches are grouped as one.

OTC defined as products free to purchase without a prescription and advertiseab to the public.

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## International Comparison Switches & Indications OTC

Anti-viral

- France/UK

Penciclovir

- Germany/UK

Aciclovir

Allergy

Multiple Mkts

Non-sedate antihistamines

- Multiple Mkts

Mild steroids (beclo)

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## DECLINE OF 3RD CLASS OF DRUGS

- Netherlands ends pharmacy only OTC
- UK expands GSL, reduces pharmacy only
- Canada now approves Dual after review
- GAO study finds it ineffective (1996)
- SWITCH study finds it outmoded nuisance

DUAL STATUS A BETTER SOLUTION

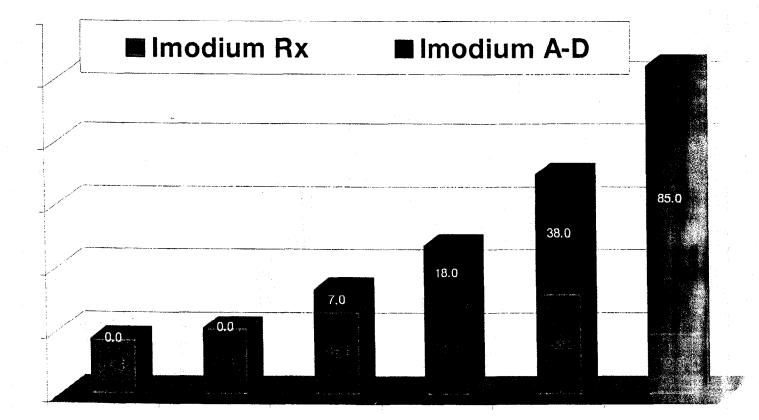
### **Dual Status Definition**

- Simultaneous Rx and OTC existence
  - with same brand name
  - with 3-6 year patent protection
- Often high dose/ low dose
- Sometimes by indication
- International experience positive -- Germany, UK, France etc.

### Imodium 86-92 Dual Statu

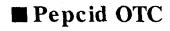
#### With **Dual Status**

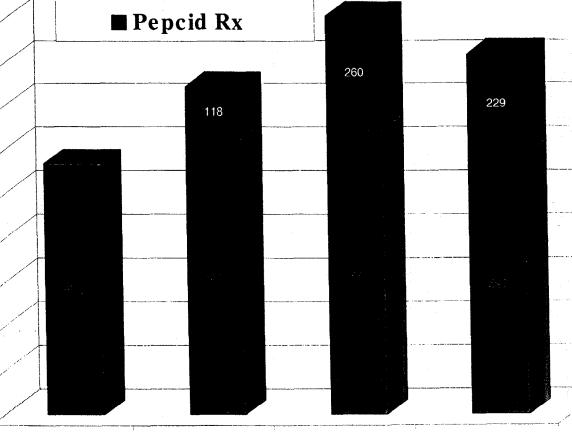
- Rx sales can continue to grow
- OTC sales can compensate for lost Rx sales over time



Pepcid 94-97 Dual Status

With Dual Status it is entirely possible to keep Rx sales momentum and control rate of decline





### Dual Status Solves Stakeholder Problems

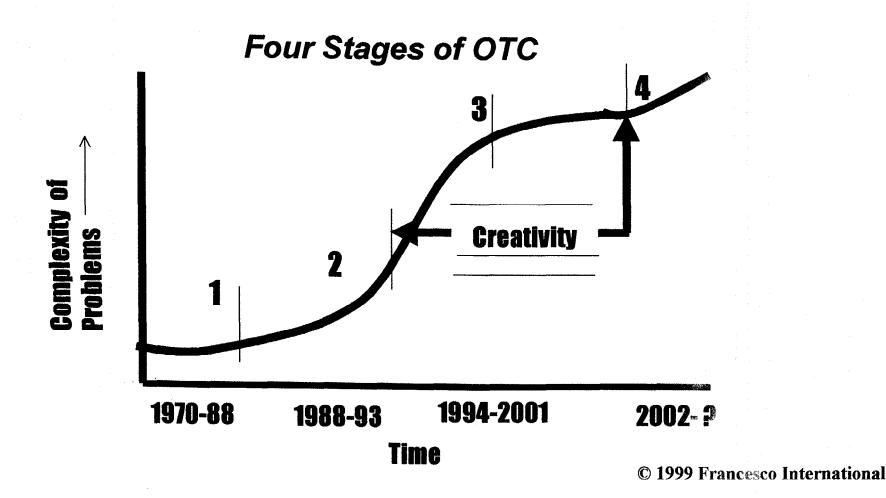
- Reimbursement can remain
- Those who don't want to see MD can buy
- Expands the market for pharma
- Managed care has options,
  - depending on diagnosis, drug alternatives
  - can create OTC reimbursement budget

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## The Four Stages of OTC Evolution

• We are Moving onto the 4th Stage of Evolution of Rx-to-OTC Switches





## **Dual Status Incentives to Pharmaceutical Companies**

Dual Status is Offensive and Defensive

_			1800	
NPV	1500			
		1300		
	Stays	Pure	Dual	
•	Rx	OTC	Status	
· · · · · · · · · · · · · · · · · · ·		Switch		

# Ten Growing & Troubling Rx Health Indications That Should Be Considered for Some Form of OTC Status

- INCONTINENCE
- ASTHMA
- HYPERCHOLESTEROLEMIA
- HYPERTENSION
- ARTHRITIS
- OSTEOPOROSIS
- MIGRAINE
- BENIGN PROSTATE HYPERPLASIA
- VIRAL INFECTIONS
- EMERGENCY CONTRACEPTION

## Francesco International Recommendation

#### PURSUE DUAL STATUS CONCEPT

- a) Review International Switch Scene
- b) Create mechanism to gain answers to chronic therapy questions
- c) Offer incentives
- d) Expand ideas like "test market" concept

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